A STUDY TO EVALUATE THE EFFECTIVENESS OF FENUGREEK ON BLOOD SUGAR LEVEL AND SYMPTOM MANAGEMENT AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS IN SELECTED VILLAGES OF DISTRICT BUDGAM.

SYNOPSIS SUBMITTED TO DESH BHAGAT UNIVERSITY MANDI GOBINDGRAH PUNJAB

IN PARTIAL FULL FILLMENT FOR THE REQUIREMENT

FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY IN

NURSING

UNDER THE GUIDANCE OF

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BACKGROUND OF THE PROBLEM

Sweetness is one of the five basic tastes and is regarded as a pleasurable experience. Foods rich in simple carbohydrates such as sugar are those most commonly associated with sweetness, although there are other natural and artificial compounds that are sweet at much lower concentrations, allowing their use as non-caloric sugar substitutes. Other compounds may alter perception of sweetness itself.

A Greek physician Arateus coined the term ‘diabetes’ means ‘siphon’ to explain “the liquefaction of the flesh and bones into urine” in the Roman era.[1] Diabetes mellitus is such a condition in which the person has high blood sugar because the body does not produce enough insulin or the cells do not respond to the insulin being secreted. If the blood sugar values are not controlled properly it may lead to diabetes related complications like diabetic retinopathy,

nephropathy, etc.

A study conducted by National Centre for Health Statistics (NHIS), Centre for Disease Control and Prevention estimated that the number of Americans with diagnosed diabetes has more than tripled from 5.6 million to 20.9 million. The estimation was done using data from the National Health Interview Survey from the NHIS. The study was conducted since 1957. The sampling technique employed was multistage probability sampling.[2]

Margaret J, McNeely and Edward J Boyko conducted a study to estimate diabetes prevalence in Asian Americans. The purpose of the study was to directly compare the prevalence of type 2 diabetes in Asian Americans with other racial and ethnic group in the US using data from the 2001 Behavioural Risk Factor Surveillance System (BRFSS). A telephone survey of the health status and health behaviours in all the 50 states was done. The study concluded that adjusted prevalence of diabetes is 60% higher in Asian Americans.[3]

As per the article in healthkart knowledge bank "effect of diabetes in India", diabetes is amongst the largest and fastest growing diseases in India with around $30 billion cost burden. 70% of the cost is because of complications due to lack of proper management of the disease. Diabetes causes significant morbidity and mortality both in urban and rural populations, with considerable loss in potentially productive years (35–64) of life – hence the need for devising appropriate strategies for their control and management. The cost implications of diabetes to society is enormous and run into thousands of crores in rupees when the direct costs to people with illness, their families, indirect costs to society, due to reduced productivity; and intangible costs, such as compromised quality of life are factored. In other words, the overall increase in GDP and life expectancy through reduction in mortality due to diabetes can be quite substantial. It is estimated that overall prevalence of diabetes is 62.47 per 1,000 people in India[4]

India, which has 61.26 million people diagnosed with type 2 diabetes (8.3% of the population), ranks second only to China in total cases and third behind the United States (10.9%)

and China in terms of prevalence. By 2030, India will have million people with type 2 diabetes, IDF projects[5].

Kashmir has a prevalence of diabetes as high as 20%- double the national average of 8%. The prevalence was 17% in urban, 10% in midland, 7% in the highland, and 4% in the plain regions. Only 40% of the people with diabetes had adequate control of blood sugar levels. In one large study, the prevalence of diabetes was 19% in rural men and 22% in rural women compared to 12% in urban men and 17% in urban women.[6]

NEED AND SIGNIFICANCE OF THE STUDY

At a global scenario, diabetes mellitus is finally being recognized as a global epidemic with a potential to cause a worldwide healthcare crisis, hence it is the need of the hour that something should be done to save people from morbidity and mortality caused by diabetes mellitus. Diabetes is an epidemic which is nearly four times as common as all types of cancer combined. It is fast becoming the 21st century's major public-health concern. Baroness Young , the chief executive of Diabetes UK, Britain's main diabetes charity and campaigning group says that diabetes is a growing crisis which is big, scary and very expensive and it is an epidemic which could bring the health services to its knees unless something is done for it.[7]

Every 10 seconds one person is dying with diabetes. Two new diabetic cases are being identified in every 10 seconds in the world. It is estimated that 7 million new diabetic cases will be identified by 2025. 80% of the diabetics in the world will

be present in developing countries like India. India is being considered as the diabetic capital of the world with Hyderabad as diabetic capital of India.[8]

Various modalities are available to treat diabetes mellitus like oral hypoglycaemic agents, insulin, exercises, complementary and alternative therapies, etc. Among the complementary and alternative therapies available for diabetes mellitus are herbs and supplements and mind-body medicine. Various botanical products are used for diabetes treatment like allivum sativum(garlic),

aloe vera, coccinia indica (ivy gourd), gymnema sylvestre (gymnema), momordica charantia (bitter melon), opuntia streptacantha (prickly pear cactus, nopal), panex ginseng, P quiquefolius (ginseng), trigonella foenum graecum (fenugreek).[9]

The present study is regarding the use of fenugreek to reduce the fasting blood sugar levels for type 2 diabetic patients.

Fenugreek (trigonella foenum graecum) is an annual plant in the family Fabaceae. The plant has small round leaves, is cultivated worldwide as a semi-arid crop, and is a common ingredient in dishes from the Indian subcontinent. Fenugreek is used as a herb as a spice and its leaves are used as a vegetable. Its seeds have distinctive cuboid-shaped, yellow to amber colour. Fenugreek seeds are thought to be a galactogogue that is often used to increase milk supply in lactating women. Fenugreek seeds are used as a natural herbal medicine in the treatment of diabetes. There are other several uses of fenugreek, for having beautiful shining hair, for skin ailments, treatment for indigestion, and to aid in labour and delivery.[10]

The major isomer 4-hydroxyisoleucine, an atypical branched chain amino acid derived from fenugreek was demonstrated to stimulate glucose-dependent insulin secretion by a direct effect on pancreatic islets. In addition to stimulating insulin activating insulin receptor substrate associated phosphoinositide 3 (PT3) kinase activity.[11]

Robert KT conducted a study on the potential of fenugreek as a functional food and nutraceutical and its effect on glycemia and lipidemia. They found that fenugreek seeds contain 45.4% dietary fibre which blunts glucose and cholesterol after a meal.[12]

Shojali A, Dabaghia FH,Goushegir , Fard MA did a systematic review of the published literature on the efficacy on the Iranian medicinal plant for glucose control in patients with Type 2 diabetes mellitus in 2011. Electronic literature searches of MEDLINE. Googlescholar. SID, Cochrane Library Database from 1966 up to June 2010 was done. Evidence of glycemic control was found in Citrullus colocynthus, Ibomoea betatas, Silybum, marancum and trigonella foenum

graecum (fenugreek).[13]

In 2009, Kassaian N, Azadbhakt L, Forghoni B, Amini G conducted a clinical trial study in Iran to study the effect of fenugreek seeds on blood glucose and lipid profiles in 24 Type 2 diabetic patients. Patients were placed on 10gms/day powdered fenugreek seeds mixed with yoghurt or soaked in hot water for 8 weeks. Results showed that fenugreek soaked in hot water decreased fasting blood sugar significantly.[14]

Kernap Sarabai L conducted a study on the effectiveness of roasted fenugreek seed powder on 40 NIDDM patients selected by quota sampling method. They were tested in M.V.R clinic Arakkonam. Pretest fasting blood sugar was done, 24 grams/day of roasted fenugreek seed powder in divided dose before breakfast and dinner for 15 days. Post test fasting blood was checked on the 16th day. There was a significant difference in blood sugar (pretest mean=155.7 SD=33.28, post-test mean

=139.75, SD=29.24) after administering roasted seed powder in experimental than control group.[15]

These studies show that fenugreek was effective in reducing the blood sugar levels of the diabetic patients. Hence, the researcher wants to test the effectiveness of fenugreek among Type 2 diabetic patients as fenugreek is a cheap substance which can be afforded by all people. Hence with the help of these seeds the blood sugar levels can be kept well under control by the patients.

Gap in Research / Knowledge

In this present setting the studies pertaining to fenugreek administration to control Blood glucose level and in managing the symptoms were not undertaken. The accessibility to healthcare facilities is very much limited to these particular villages. Hence by conducting this study in these areas will enable the clients with diabetes to practice this home remedy which in turn will help them to maintain the blood glucose levels with in optimal limits.

Moreover fenugreek is commonly available edible item which is used in day today cooking

purposes which is cheaper and easily available. Hence using this intervention will be a cost effective as well as no side effect intervention among the clients with diabetes. Hence the researcher selected this study on priority base which will serve as evidence based practice in the community areas.

STATEMENT OF THE PROBLEM

A study to evaluate the effectiveness of fenugreek on blood sugar level and level of symptoms among patients with Type 2 diabetes in selected villages of District Budgan.

OBJECTIVES

1. To assess the fasting blood sugar level and level of symptoms of the diabetic patient's before administering fenugreek.
2. To assess the fasting blood sugar level and level of symptoms of the diabetic patient's after administering fenugreek.
3. To determine the difference in blood sugar level before and after administering fenugreek in the experimental group.
4. To compare the post-test fasting blood sugar level and level of symptoms between the experimental and control groups.
5. To associate the pre-test fasting blood sugar level and level of symptoms with selected demographic variables (age, sex, occupation, education and religion in both the groups).
6. To correlate the pretest posttest blood sugar level and the level of symptoms in the experimental and control group.

OPERATIONAL DEFINITIONS:

Effectiveness: It is the result or consequence of an action (Oxford dictionary).

In this study, it is the capability of producing a change in the blood sugar level with administration of fenugreek.

Fenugreek: Herb having off-white flowers and aromatic seeds used medicinally and in curry (freedictionary.com).

In this study, 10 grams of fenugreek seeds will be soaked overnight in a glass of hot water for 10 hours. The water along with the fenugreek seeds will be given by the investigator to the client on empty stomach for 14 days.

Type 2 Diabetes patients: It results from insulin resistance, a condition in which cells fail to use insulin properly, sometimes combined with an absolute insulin deficiency (Wikipedia)'.

In this study it refers to the patients who are diagnosed to have Type 2 diabetes mellitus and are on treatment for the same.

Blood sugar level: It is the amount of glucose (sugar) present in the blood of a human (Wikipedia).

In this study it refers to fasting blood sugar level 120 and above. It is measured by glucometry on the first and fifteenth day.

Level of symptoms : it is the list of symptoms present among the patients with diabetes as measured by a modified diabetes symptom checklist designed by (snoek. j. frank) which is a 21 item scale rated on a 5 point likert scale. How much trouble have these symptoms given you over the last two weeks?

Villages: - A village is a clustered human settlement or community, larger than a hamlet but smaller than a town (although the word is often used to describe both hamlets and smaller towns), with a population typically ranging from a few hundred to a few thousand. (Wikipedia).

It refers to the person with diabetes living in same settings with same culture, custom, norms and having same geographical boundries, road connectivity, health facility, power facility and water facility. Here village refers to S.K. Pora, Razven, Russu, Kanihama, and Malpora etc.

Community Setting:- A community is a social unit with commonality such as norms, religion, values, customs, or identity. Communities may share a sense of place situated in a given

geographical area or in virtual space through communication platforms. (Wikipedia)

It refers to people living in the same area sharing and interacting with each other and having same basic facilities with common social amenities and organizations.Here it refers to Magam block.

ASSUMPTIONS

Assumptions are statements that are taken for granted or are considered true, even though they have not been scientifically tested.[20]

This study assumes that:

1. Fenugreek may have an effect on glycemic levels of individuals.

2. Fenugreek may help in reducing the blood sugar levels among Type 2 diabetic patients.

HYPOTHESIS

A hypothesis is a tentative prediction or explanation of the relationship between two variables.[16]

The following hypotheses are postulated and will be tested at 0.05 level of significance:

- **H_1**: There is a significant difference in blood sugar level and level of symptoms between pretest and posttest in the experimental group among patients with diabetes.
- **H_2**: There is a significant difference in the post-test blood sugar level and level of symptoms between the experimental and control group among patients with diabetes.
- **H_3**: There is a significant association between pretest level of blood sugar, symptoms level and selected demographic variables among patients with diabetes in the experimental and control group respectively.
- $H_{4:}$ There is a significant relationship between the post test blood sugar level and level of symptoms among the patients with diabetes in the experimental and control group respectively.

DELIMITATIONS

The study was delimited to:

- Patients having Type 2 diabetes mellitus.
- Patients on any one oral hypoglycemic agents.
- Patients not having any bleeding disorder.
- Patients not on warfarin, aspirin, or any other Coumadin derivatives.

CONCEPTUAL FRAMEWORK

Conceptual frameworks (theoretical frameworks) are a type of intermediate theory that attempt to connect to all aspects of inquiry (e.g., problem definition, purpose, literature review, methodology, data collection and analysis). Conceptual frameworks can act like maps that give coherence to empirical enquiry. Because conceptual frameworks are potentially so close to empirical inquiry, they take different forms depending on the research question or problem.[21]

The conceptual framework of the present study is based on Kenny's Open System model. This study is focused on the effectiveness of fenugreek on the blood sugar levels among Type 2 diabetic patients. The system's theory is concerned with changes due to interrelation between various factors in a situation. All living systems are open, in which there is a continual exchange of matter, energy and information. The concepts of Kenny's open systems model are input, throughput, output and feedback.

LITERATURE REVIEW

The literature in this chapter has been divided into the following headings;

1. Literature related to diabetes mellitus.
2. Literature related to fenugreek
3. Literature related to effectiveness of fenugreek on diabetes mellitus.

LITERATURE RELATED TO DIABETES MELLITUS

M. Latha and Sajithkumar P conducted a descriptive study to measure the quality of life of patients with diabetes mellitus in Calicut. A standardized QOL scale developed by Ferrans and Powers which consisted of two sections; section A with 34 items on the level of satisfaction obtained by patients and section B with the 34 items indicating the level of importance given by the patient was used. The items were grouped into five domains namely personal health, family life, social support, role performance and psychological wellbeing. 30 subjects were selected by convenient sampling both from hospital in-patient and out-patient department. The findings showed that there is a positive correlation between the levels of satisfaction and there was a negative correlation between the age of the patients and their QOL score. Older patients had lesser QOL scores than younger adults.[17]

Melba Sheila DeSouza and K Subrahmanya Nairy did a quasi-experimental study to determine the health promoting behaviours and quality of life among adults with diabetes mellitus in Hyderabad after nurse directed intervention. The objective of the study was to determine the health promoting behaviours (HPB) and quality of life of adults with diabetes before and after the nurse directed intervention as measured by health promoting behaviours and Ferrans and Powers Quality of Life Index Diabetes III version tools and to evaluate the effectiveness of the nurse-directed intervention (NDI) in terms of improvement in the health promoting behaviours and quality of life of the adults with diabetes. 30 samples each with diabetes were selected by convenient sampling in the experimental and control group. Subjects above the age of 20 who were able to understand, read, write and communicate in English were selected. Pre-test was given to the experimental and control group, following which nurse directed intervention was given to the experimental group. The nurse directed intervention was again reinforced after two months to the experimental group. The post-test was conducted four months after the pre-test for both the experimental and control groups. The results showed that

there was a significant difference in the post- test total of QOL (11.28, p=0.001) as well as HPB were higher among the diabetics in the experimental group (134.13) compared to the control group (92.37), (6.26, p=0.001). Thus the study concluded that the nurse directed intervention was effective in raising the quality of life as a whole.[18]

Chithralekha L, Beena M. R and Sajithkumar S conducted a quasi- experimental study in Sreekariyam Panchayat of Thiruvananthapuram district, to evaluate the effectiveness of educational programme on knowledge and practice in the control of Type 2 diabetes mellitus among patients and prevention among pre-diabetic individuals of selected families. An interview schedule was used to assess the knowledge and practice of diabetic patients regarding control of diabetes. Pre-diabetic individuals were identified by checking fasting blood glucose using a glucometer whose knowledge and practiced was assessed by using a separate interview schedule which was followed by an educational programme. Post-test was conducted after two- weeks using same pretest protocol. The pre-test scores showed that 64% of the diabetics and 56.35% of the pre-diabetics had only an average knowledge regarding the control and prevention of diabetes. The post-test score showed that the knowledge and reported practice of patients and pre-diabetic individuals were improved and the observed difference was statistically significant ($p<0.0001$).[19]

LITERATURE RELATED TO FENUGREEK

According to DigHerbs there are many uses of fenugreek. It quotes that fenugreek herbal tea is used to reduce fever and menstrual pains. It can also be used to increase the milk supply in nursing mothers. It has also been used as a digestive aid and it also contains compounds that make it an excellent expectorant to use for lung and sinus congestion. Externally, fenugreek seeds are soaked then powdered for use in lip balm and tonic. It can be very effective as a poultice for abscesses, carbuncles, boils and more. Roasted fenugreek seeds are ground to flavour curry mixtures. The seeds are also said to be aphrodisiac and increases the libido. It is also used

to add flavour to confections and pastries. Nutritionally, it is a great source of iron, thiamine, silicon, selenium and sodium.[20]

The article titled 'Mankind's Old Friend Fenugreek' in Our Food says that fenugreek is widely used in Ayurvedic medicine and cooking since 4000 years. Fenugreek is known as a warming digestive herb and galactogog. It has a high affinity for yeasts which are helpful in the digestive process as well as for fermenting process for baking idlis or dosas. Fenugreek is a great adaptogen, and its supportive function in the intestine cleans out impacted matter in the mucous membrane while adding a protective gum of its own on the walls of the intestine. The mucilagins in fenugreek (galactomannans) stimulate production of fluids, which also flush allergens from the respiratory tract, making it useful for bronchitis and congestion. It also reduces fevers and relieves inflammation. Fenugreek sprouts are high in vitamin A, C and B as well as iron, calcium, silicon, selenium and high levels of protein, most notably the amino acid 4-hydroxyisoleucine which increases production of insulin when blood sugar is high, making it very useful to treat diabetes. It is also considered to be effective in weight loss while significantly reducing cardiac risk factors. Fenugreek's ability to fix nitrogen as well as being a galactogogue has made it useful in agriculture for the land as well as for cattle fodder. Fenugreek is also used as a substitute for cod-liver oil in the treatment for rickets.[21]

Regan Hennessy in an article titled 'Benefits of fenugreek for women' says that fenugreek is commonly used to stimulate milk production in women. Milk production generally increases within one to three days after starting the supplement. Michael Castleman, a physician says that fenugreek contains diosgenin that mimics the estrogen in our body which helps to minimize the effects of hot flashes and menstrual cramps.[22]

Turkyilmaz C, Onal E, Hirfanoglu IM, Turan O, Koc E, Atalay Y et.al conducted a study in Turkey in 2011 to assess the effect of galactogogue herbal tea on breast milk production and short-term catch-up of birth weight in the first week of life. The aim of the study was to evaluate

whether consumption of maternal herbal tea containing fenugreek had any effect on breast milk production and infant's weight gain pattern in the early post natal period. Sixty six mother-infant pair was randomly assigned to 3 groups: group1 (n=22) receiving herbal tea containing fenugreek, group 2 (n=22) and group 3 (n=22) were assigned as placebo and controls respectively. Birth weight loss of birth weight, time of regain of birth weight, amount of breast milk assessed on the third day of delivery were determined. The results found that maximum weight loss was significantly lower in infants in group 1 compared to groups 2 and 3 ($p<0.05$). The infants of group 1 regained their birth weight earlier than those in the other two groups. The mean measured breast milk volume of the mothers who received galactagogue tea was significantly higher than the placebo and control groups.[23]

Hasani-Ranjbar S, Nayebi N, Moradi L, Mehri A, Larijani B, Abdollahi M conducted a systematic review on the efficacy and safety of herbal medicines used in the treatment of hyperglycemia. PubMed, Scopus, Google Scholar, Web of Science and IranMedex databases were searched upto 11th May 2010. The search terms were 'hyperlipidemia' and 'herbal medicine', medicine traditional', 'extract plant' without narrowing or limiting search elements. Fifty three relevant clinical trials were reviewed for efficacy of plants. The study showed significant decrease in total cholesterol and LDL cholesterol after treatment with a number of medicinal plants in which fenugreek was also included.[24]

LITERATURE RELATED TO EFFECTIVENESS OF FENUGREEK ON DIABETES

The Times of India reported that consuming 5 grams of fenugreek seeds daily helps in reducing the blood sugar levels. 30 people above age 30 were given fenugreek seeds for a week and the results were significant.[25] Losso JN, Holliday DC, Finley JW, Martin RT, Rood JL, Yu Y, Greenway FC did a study on fenugreek bread: a treatment for diabetes mellitus in Food Science Department, Lousiana State University Agricultural Centre, USA. They assumed that since fenugreek has a bitter taste people disagree to consume it. So they developed a fenugreek

bread formula that was produced in a commercial bakery. A double-blinded randomized controlled study in which eight diet controlled diabetic subjects were served two slices (56g) and 5% fenugreek. Blood glucose and insulin was tested 4 hours after consumption. Tests were done one week apart, once with the fenugreek bread and once with regular bread. The area under the curve for glucose and insulin was lower in the fenugreek condition, but only reached significance with insulin. The study concluded that acceptable baked products can be prepared with added fenugreek which will reduce insulin resistance and type 2 diabetes.[26]

Kassain N, Azadbakht L, Forghani B, Amini M did a study on the effect of fenugreek seeds on blood glucose and lipid profiles in type 2 diabetic patients in Iran. They did clinical trial study in which 24 type 2 diabetic patients were placed on 10 grams/day powdered fenugreek seeds mixed with yoghurt or soaked in hot water for 8 weeks. Weight, FBS, HbA1c, total cholesterol, LDL, HDL and food record were measured before and after the study. The findings showed that fasting blood sugars, triglycerides and VLDL-c decreased significantly (25%, 30% and 30.6% respectively) after fenugreek soaked in hot water whereas there were no significant changes in lab parameters in cases consumed it mixed with yoghurt.[18]

A H Zargar,Anjili Nehru, B.A Laway, F.A Dar conducted a comparative study on the effect of consumption of powdered fenugreek on the blood sugar and HbA1c levels in patients with Type 2 diabetes mellitus in Srinagar using convenient sampling and those who were fit as per the sampling criteria. They were divided into three groups comprising of 14 each. Group I was given 10 grams, group II 20 grams and group III none. The HbA1c was tested initially and after six weeks. The BSL's were periodically assessed. The results showed significant drop in FBS in Group II.[27]

Analava Mithra conducted an experimental study on the effects of fenugreek in Type 2 diabetes and dyslipidemia in Bengal. 80 subjects were randomly selected. Patients were divided into two groups of 40 each. 40 patients of a group were randomly sub-divided into 4 subgroups

each containing 10 patients. Each group was given 25 grams, 50 grams, 75 grams and 100 grams fenugreek divided in equal doses fifteen minutes before breakfast, lunch and dinner respectively mixed with water as a drink. The preparation was made salty or sour, according to individual choice. Patients in the control group received normal diet in the period of study. Comparison of the study and control groups showed significant decrease in fasting blood sugars in groups receiving 25 grams, 50 grams and 75grams of fenugreek after 2 years.[28]

Sharma RD, Raghuram TC and Rao NS conducted a randomized controlled crossover trial in which 10 participants with Type I diabetes were asked to consume a daily quantity of fenugreek seeds powder divided for lunch and dinner and a placebo for 10 days. By the end of the study significant improvement was noted in the fenugreek group in several parameters: a 54% reduction in 24 hour urine glucose levels and mean reduction in glucose tolerance test values and fasting serum glucose levels.[29]

METHODOLOGY

RESEARCH APPROACH

In view of the nature of the problem chosen, an evaluative approach was chosen in order to meet the objectives of the study was to assess the effectiveness of fenugreek on blood sugar levels among Type 2 diabetic patients.

RESEARCH DESIGN

A research design encompasses the methodology and procedures employed to conduct scientific research.

The research design used for this study was quasi experimental design

E: O_1 X O_2

C: O_1 O_2

KEY

E - Experimental group

C - Control group

O_1 - Fasting blood sugar level and level of symptoms before administering fenugreek.

O_2 - Fasting blood sugar and level of symptoms after administering fenugreek.

X - Administration of plain fenugreek soaked in hot water (10gm X 2 weeks).

VARIABLES UNDER STUDY

Variables are qualities, properties, or characteristics of persons, things, or situations that change or vary.[20]

The variables mainly included in the study are:

Independent variable: It is a stimulus or activity that is manipulated or varied by the researcher to create the effect on the dependent variable. In this study the independent variable was fenugreek soaked in hot water.

Dependant variable: It is the outcome or response due to the effect of the independent variable, which researcher wants to predict or explain. In this study, the dependent variable was fasting blood sugar level.

SETTING OF THE STUDY

The location for conducting a study is termed as setting of the study. The study will be conducted in ten villages of tehsil Beerwah which includes Sanoora Kalipora (2744), Kawosa(6123), Sozeith(8171), Russu(2969), bundgam(2862). The total population of beerwah tehsil is one lakh, sixty three thousand, three hundred and thirty three. The total population suffering with diabetes in beeerwah tehsil is 3757(2.3%) as per census 2011.However The Village wise diabetic cases will be found after data collection. There are twenty thousand, nine hundred and fourteen households in tehsil beerwh district budgam. The main occupation of tehsil beeerwah is farming. The people belonging to beerwah tehsil earn their bread and butter by

means of farming and laboring. So the main income generates from agriculture work.

POPULATION

A population is the entire aggregation of cases in which a researcher is interested.[51]

Target population

The target population is the aggregate of cases about which the researcher would like to generalize. In this study, all the residents with Type 2 Diabetes will be the target population.

Accessible population

The accessible population is the aggregate of cases that conform to designated criteria and that are accessible for study[20]. In this study, patients with Type 2 diabetes in Sanoora Kalipora, Kawoosa, Russsu, Sozeith and Bundgam, villages of Tehsil Beeerwah Budgam.

SAMPLE AND SAMPLING TECHNIQUE

Sample may be defined as representative unit of a target population, which is worked upon by researchers during their study.[20]

300 patients with type 2 diabetes and those who met the inclusion criteria were selected. 150 patients in the experimental group and 150 patients in the control group.

Probability sampling simple random sampling technique will be used to select 300 patients with type 2 diabetes from Sanoora Kalipora, Kawoosa, Russsu, Sozeith and Bundgam, villages of Budgam district.

Inclusion criteria

- Type II diabetic patients those who are willing to participate in the study.
- Patients between the age group of 30 to 70 years.
- Patients whose blood sugar levels were above 120mg/dl.
- Patients who were on only one hypoglycaemic agent.

Exclusion criteria

- Patients on insulin.
- Patients on warfarin, aspirin or Coumadin derivatives.
- Patients with bleeding disorders.
- Patients with arthritis.

TOOL AND TECHNIQUE

Data collection instruments are the strategy or system used to gather information from participants, programmers and other elements of evaluation.

The tool consisted of structured interview and biophysiological measurement (glucometer)

Part I: Demographic variables

Part II: Clinical variables

Part III Modified Diabetes Symptom Checklist (Originally developed by SAnoek. J. Frank)

DESCRIPTION OF THE TOOL

Part I consisted of 16 items regarding age, gender, religion, educational status, type of work, income, food habits, personal habits, duration of illness, duration of treatment, history of medical illness, family history of diabetes mellitus, height, weight and body mass index.

Part II consisted of fasting blood sugar level assessment with glucometer. The level of hyperglycemia will be classified as

70-120 mg/dl	:	Normal blood sugar level
121-150mg/dl	:	Mild hyperglycemia
151-250 mg/dl	:	Moderate hyperglycemia
>250mg/dl	:	Severe hyperglycemia

Part III consisted of a Modified Diabetes Symptom Checklist originally developed by Snoek. J Frank. The checklist consisted of 21 items based on the symptoms of the patients. It had a score range of 1 to 5 for each item, the range of possible scores for the symptoms ranged from a minimum of 0 to a maximum of 105.

1 - Not at all

2 - A little

3 - Moderately

4 - Very

5 - Extremely

The gradings of the symptoms were under the following headings:

0-30	:	Mild hyperglycemia
31-70	:	Moderate hyperglycemia
71-105	:	Severe hyperglycemia

Testing of the tool

CONTENT VALIDITY

Content validity is concerned with scope of coverage of the content area to be measured**.**

Content validity is based on the extent to which an instrument adequately represents the universe of content for the concept being measured. The content validity of the tool will be obtained from 7 experts in the field of Medical-Surgical Nursing, Endocrinologist and Statistician for relevance, appropriateness, accuracy of the items and for further modifications. Suggestions and opinions of the experts will be considered and changes will be made.

RELIABILITY OF THE TOOL

Reliability is the degree of consistency with which the attributes or variables are measured by an instrument.

Test –retest method will be used to assess the reliability of the instrument. Karl Pearson's

Co-effiecient of Correlation will be calculated.

PILOT STUDY

A pilot study is referred to a small-scale preliminary tryout of the method to be used in an actually large study, which acquaints the researcher with problems that can be corrected in proportion for the large research study or is done to provide the researcher with an opportunity to try out the procedure, method, and tools of data collection.[8]

A pilot study will be conducted in Shipora, and Ruseu community areas of Budgam district. Random sampling will be as used to select 30 subjects, 15 in the experimental group and 15 in the control group.

DATA COLLECTION PROCESS

Data are the observable and measurable facts that provide information about phenomenon under study. Permission will be obtained from the Budgam District sarpanch for the study. 300 subjects will be taken for the study. Prior informed consent will be taken from the study subjects before commencing the study. On the first day pre-test fasting blood sugar level and symptom management will be measured after which fenugreek soaked in hot water will be administered for 14 days. On the fifteenth day post-test fasting blood sugar along with symptom management will be assessed.

PLAN FOR DATA ANALYSIS

Data analysis is the process of organizing and synthesizing the data so as to answer research questions and test hypothesis.[20]

- The demographic data will be presented by using frequency distribution, tables and graphs. The level of hyperglycemia will be presented by means of descriptive statistics, mean and standard deviation.
- The effectiveness of fenugreek will be established by means of 'paired t test'.
- Association between various demographic variables and blood sugar levels will be

established by Chi Square analysis.

PROTECTION OF HUMAN RIGHTS

Human rights are commonly understood as inalienable fundamental rights to which a person is inherently entitled simply because she or he is a human being. Hence a written consent of the subjects will be taken before the study was started and debriefing will be done after the study is completed. Confidentiality and anonymity of the study subjects will be maintained throughout the study

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